UTS UNIVERSITY OF TECHNOLOGY SYDNEY

Measuring the value and effectiveness of ventricular assist device therapy in the Australian health care setting

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Thesis submitted in fulfilment of the requirements for
the degree of Doctor of Philosophy under the supervision of
Professors Christopher Hayward and Patricia Davidson

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Certificate of Original Authorship

I, *Roslyn Prichard* declare that this thesis, is submitted in fulfilment of the requirements for the award of Doctor of Philosophy, in the Health Faculty at the University of Technology Sydney.

This thesis is wholly my own work unless otherwise referenced or acknowledged. In addition, I certify that all information sources and literature used are indicated in the thesis.

This document has not been submitted for qualifications at any other academic institution.

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Author signature

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(Roslyn Prichard)

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1.1 Acknowledgements:

No (wo) man is an island. [1]

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My family and friends have supported me on this long road, no questions asked, buoying me up with their love and belief. Most especially I acknowledge the support and love that has kept me sane every day of this journey-my best beloved Sal (and Fleagle!)

[1] Adapted from *Devotions upon Emergent Occasions.*

John Donne 1624

1.2 Anthology of publications and presentations:

1.2.1 Publications associated with this thesis

Prichard R et al. Left Ventricular Device Implantation Impacts on Hospitalisation Rates, Length of Stay and Out of Hospital Time. *Heart, Lung and Circulation* (2018) Volume 27, Issue 6, Pages 708-715.

Prichard R et al. Combining institutional and administrative data to assess hospital costs for patients receiving ventricular assist devices. *International Journal of Technology Assessment in Health Care*. (2018).34(6):555-566

Prichard R, et al. Costs Before and After Left Ventricular Assist Device Implant and Preceding Heart Transplant: A Cohort Study. *Heart, Lung and Circulation* (2019), *In Press*

Prichard R, et al. Examining discrepancies between clinician proxy estimates and patient reported quality of life in heart failure*: Circulation: Cardiovascular Quality and Outcomes*. 17/09/2019. *Submitted* manuscript ID: CIRCCQO/2019/006160

NB: Published papers in PDF format (N=4) are attached as Appendices 1-4

1.2.2 Accepted abstracts for oral presentation as part of this thesis

Prichard et al. Impact of left VAD implantation on hospitalisation, and readmissions using a linked administrative dataset: *Cardiac Society of Australia and New Zealand***. Adelaide August 2016. Heart, Lung and Circulation -Volume 25: S114**

Prichard et al. Frailty and quality of life in advanced heart failure and transplant medicine- do we need to screen? *Cardiac Society of Australia and New Zealand***. Brisbane August 2018. *Heart, Lung and Circulation -Volume* 27: S101**

Prichard et al. Mind the gap: Clinician perceptions of quality of life in advanced heart failure. What are we missing? *Cardiac Society of Australia and New Zealand***. Brisbane August 2019. Heart, Lung and Circulation -*Volume* 28: Supplement 4, S182**

NB: Abstracts accepted for oral presentation (N=3) are attached as Appendix 8

1.2.3 Abstracts accepted for poster presentation as part of this thesis

Prichard et al, Bottom-up costing ventricular assist device therapy and Optimal medical management-first Steps to establishing cost effectiveness. *Quality of Care and Clinical Outcomes conference***. Baltimore, USA June 2014** ***Circulation: Cardiovascular Quality and Outcomes. 2014;7:A253***
https://www.ahajournals.org/doi/abs/10.1161/circoutcomes.7.suppl_1.253

Prichard et al, Establishing institutional costs in the year before and after VAD implant and before heart transplant. *International Society for Heart and Lung Transplantation*. **Washington, DC, USA April 2016,** ***The Journal of Heart and Lung Transplantation, Volume 35, Issue 4, Supplement, Page S272***
https://www.jhltonline.org/article/S1053-2498(16)00820-2/fulltext

Prichard et al: *International conference on Frailty &Sarcopenia Research,* **Barcelona, Spain 2017** ***The Journal of Frailty and Ageing*** **V6: S235,**

Prichard et al, Quality of life in advanced heart failure- disconnect between patients' and clinicians' perceptions, independent of clinician experience: *European Society of Cardiology-Heart Failure Congress*, **Paris , France August 2017.** ***European Journal of Heart Failure Volume 19 Supplement. S1, P 1049***

Prichard et al, Frailty is associated with reduced patient reported quality of life in advanced heart failure patients and clinicians are poor at identifying it: *Annual Meeting of the Australian and New Zealand Society for Sarcopenia and Frailty Research (ANZSSFR),* **Adelaide November 2017** ***Australasian Journal on Ageing 2018, Volume 37: Issue S1 P54*** https://onlinelibrary.wiley.com/doi/10.1111/ajag.12508

Prichard et al, Estimating Quality of Life among advanced heart failure patients: What could formal screening add to clinical assessments**:** *Cardiac Society of Australia and New Zealand***. Brisbane August 2018.** ***Heart, Lung and Circulation -Volume 27: Supplement 2, S384***

Prichard et al, Estimating quality of life in advanced heart failure- Can we differentiate excellent clinician proxies**:** *International Society for Phamacoeconomic and Outcomes Research***. Asia Pacific- Tokyo September 2018,** ***Value in Health Volume 21, Supplement 2, S32***

NB: Abstracts accepted for poster presentation (N=7) are attached as Appendix 9

1.3 Awards granted as part of this thesis

1. Cardiac Society of Australia and New Zealand (CSANZ) Heart Failure Council Henry Krum memorial Travel Grant/ ECS Heart Failure (2018)
2. National Health and Medical Research Council Postgraduate scholarship, Dora Lush Stipend (2017)
3. UTS Business school research grant (2016)
4. Health Services and Practice Research Student Development Award (HSP)
5. Health Faculty travel and research Grant

1.4 Table of Contents:

Table of Contents

NB: Throughout this thesis table and figure numbers have been updated from their original published version so as to maintain sequential appearance throughout the document. Typographical errors in the published scripts have been corrected in the chapters and common abbreviations synchronised across the papers. Data mentioned in the text of Chapter 4 but not in published tables has been added as Appendix 7.

Finally reference lists have been updated to include chapter introductions and chapter conclusions, as well as operational URLs.

1.5 List of Tables:

1.6 List of Figures

1.7 List of Appendices:

1.8 Acronyms and Abbreviations:

A10Z	ArDRG code for ventricular assist device implantation admission
ABF	Activity based funding
ACT	Australian Capital Territory
AHF	Advanced heart failure
AMI	Acute myocardial infarction
ANZCOTR	Australia and New Zealand Cardiothoracic Organ Transplant Registry
APDC	Admitted patient data collection (Australia)
ArDRG	Australian refined diagnosis related group
BiVAD	Biventricular assistance
BMI	Body mass index
BTC	Bridge to candidacy
BTT	Bridge to transplant
BTT-VAD	Bridge to transplant ventricular assist device
C-Pulse	Extra aortic counter pulsation device
CCL	Cardiac catheter laboratory
CCU	Coronary Care Unit
CEA	Cost effectiveness analysis
cf-VAD	Continuous flow ventricular assist device
CHeReL	Centre for Health Record Linkage (Australia)
CTCR	Cost to charge ratio
CUA	Cost utility analysis
DALY	Disability adjusted life year
DFR	Detailed file review
DMI 10	Depression in the medically ill questionnaire

DRG	Diagnosis related group
DT	Destination therapy
DT-VAD	Destination therapy ventricular assist device
ECMO	Extra corporeal membrane oxygenation
ED	Emergency department
EDDC	Emergency department data collection (Australia)
eGFR	Estimated glomerular filtration rate
EQ5D 5L	Euroquol five domains, five levels
EUROMACs	European Registry for Patients with Mechanical Circulatory Support
HF	Heart failure
HFpEF	Heart failure with preserved ejection fraction
HM2	Heartmate 2 VAD
HM3	Heartmate 3 VAD
HRQoL	Health related quality of life
HTA	Health technology assessment
HTx	Heart transplantation
HW	Heartware VAD
IC	Impaired cognition
ICD	International classification of disease
ICER	Incremental cost effectiveness ratio
ICU	Intensive care unit
IDMT	Inotrope dependent medical therapy
IHD	Ischaemic heart disease
IHPA	Independent Hospital Pricing Authority
IMACs	International Society for Heart and Lung Transplantation Mechanically Assisted Circulatory Support registry
INTERMACs	Interagency Registry for Mechanically Assisted Circulatory Support

IQR	Interquartile range
IRG	Inter rater gap
J-MACs	Japanese registry for mechanical assisted circulatory support
LOS	Length of stay
LVAD	Left ventricular assist device
MBS	Medical benefits scheme (Australia)
MoCA	Montreal cognitive assessment
MPAP	Mean pulmonary arterial pressure
MSAC	Medical Services Advisory Committee
NEP	National efficient price
NHCDC	National hospital cost data collection (Australia)
NHS	National Health Service (UK)
NIS	National inpatient sample (US)
NSW	New South Wales
NWAU	National weighted activity unit
NYHA	New York Heart Association
OMM	Optimal medical management
OOH	Out of hospital time
PAWP	Pulmonary arterial wedge pressure
PMSI	Program for the medicalisation of information systems (France)
PRO	Patient reported outcome
PROM	Patient reported outcome measure
prQoL	Patient reported quality of life
QALY	Quality adjusted life year
QoL	Quality of Life
RVU	Relative value unit
TAH	Total artificial heart

TDABC	Time driven activity based costing
TGA	Therapeutic Goods Administration
TMS	Theatre management system
UK	United Kingdom
US	United States
VAD	Ventricular assist device
VBHC	Value Based Health Care

1.9 Abstract:

Heart failure is a common, costly and burdensome condition for individuals, health care systems and societies. Multiple innovations, both pharmacological and non-pharmacological, have transformed care for millions around the world. Ventricular assist devices (VADs), as one of these new technologies, have saved many lives and bridged many to transplantation, while improving quality of life. VAD registry and clinical trial data are providing a roadmap for clinicians in their effective and most appropriate use, but the implementation of evidence based interventions requires consideration of patient, provider and system characteristics.

Australia supports a system of universal health coverage, yet has challenges in ensuring equity of access to care. Complex and fragmented funding models challenge an integrated understanding of the total costs associated with care pathways. A number of regulatory, and comprehensive health technology assessment processes inform policy and funding, and costing methods specific to local care models, are critical to inform health services planning.

As health care systems around the world examine value-based funding models, understanding patient preferences is also important. Many clinical trials do not include comprehensive economic analyses nor consider incentives for, and barriers to achieving access across health systems and funding models. Communicating the value of an intervention to improve quality of life, requires consideration of patient, provider and population preferences.

This thesis is comprised of a number of discrete yet linked studies that sought to address the following questions,

1. How can linked data be used to establish costs and hospitalisation across different institutions in the years preceding and following VAD implant?
2. What is the relationship between VAD therapy as a bridge to transplant and overall heart failure hospitalisation and management costs compared with medical management?
3. What are the direct costs of managing advanced heart failure and VAD therapy in a quaternary specialist heart failure centre?
4. Could proxy quality of life assessments provided by clinicians for their heart failure patients provide useful utility estimates?

Four studies were undertaken, and a brief statement of findings is given below.

Study 1: Methods:

Linked administrative data provides a useful adjunct source for imputing costs external to the implanting centre, and combined with institutional data can illuminate both the pathways to transplant referral and the hospital activity generated by patients experiencing the terminal phases of heart failure in the year prior to transplant, cf-VAD implant or death.

Study 2: Hospitalisation:

Higher pre-implant hospitalisation in VAD patients reflects higher clinical acuity and implant is significantly associated with reduced admissions, and hospitalisation once reconditioning has occurred.

Study 3: Costs:

Once discharged home VAD implant stabilises hospital costs compared with accelerating costs in the year preceding implant. A high proportion of the hospital costs in the pre-implant year occur outside the implanting centre and should be considered in economic models assessing the impact of VAD implant.

Study 4: Proxy Quality of Life:

Clinicians in our sample tend to overestimate prQoL in heart failure patients, with patient sex, depressed mood and measured frailty all worsening the inter rater gap

1.9.2 Implications for policy, practice, education and research.

This thesis has shown the power of data to enrich clinical decision-making, as well as ensure policy and funding decisions are strategic, evidence based and reflect the needs of patients, families, communities, and clinicians. Progressing value-based health care remains a challenge requiring a commitment to rigorous studies within the framework of economic evaluation. In establishing the comparator populations, future cost effectiveness studies investigating VADs in advanced heart failure, should consider the costs and hospitalisations accrued at institutions other than the implanting centre. Formal screening for quality of life in this cohort would support reimbursement decisions and enhance shared decision-making in heart failure with real world patient reported outcomes data. Such data could impact patient selection, pre- conditioning pathways and the timing of implantation which could all impact the cost and effectiveness of ventricular assist device therapy in advanced heart failure.